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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,050	02/12/2001	William J. Boyle	A-570B	7999

7590 05/05/2003

AMGEN INC.
U.S. Patent Operations/ TJG
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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	11

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/779,050	BOYLE ET AL.	
	Examin r	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondenc address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *19,20,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-30 are pending in the instant application. Claims 1, 7-10 and 18 have been amended as requested by Applicant in Paper Number 10, filed February 13, 2003.

Claims 19, 20, 29 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1-18 and 21-28 are currently under examination.

Information Disclosure Statement

2. Applicants state on page 5 of the amendment that a supplemental IDS containing reference WO 00/24782 and Form 1449 was provided to the Office on February 12, 2002, however, the only IDS present in the file was filed on May 10, 2001.

Sequence Listing

3. The sequence listing submitted with the amendment has been entered.

Withdrawn Objections to Specification and Claims

4. The objections to the specification and the claims are withdrawn in view of Applicants' amendment.

Withdrawn Rejections

5. The rejection of claims under 35 USC § 102 is withdrawn in view of Applicants' amendment. As amended, the claims are interpreted as consisting of the amino acid sequences of SEQ ID NOS: 45 and/or 46 and heterologous amino acid sequences, and therefore the Bram et al. reference is no longer prior art.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18 and 21-28 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions of matter comprising the complete extracellular domain of the AGP-3 receptor protein and a vehicle, does not reasonably provide enablement for compositions of matter (including pharmaceutical compositions) that comprise portions of the extracellular domain and a vehicle, for reasons of record in Paper No. 9 at pages 4-6, and below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants traverse the rejection and assert that the rejection alleged that it would require undue experimentation to practice the invention, and cite *Ex parte Jackson, Ansul v. Uniroyal* and *In re Ranier*. Applicants assert that the specification teaches how one can make various modifications to the polypeptides to develop alternative sequences that function as a binding

partner to AGP-3, and such changes can be made by routine mutagenesis, the polypeptides expressed by routine expression systems, and the activity of the polypeptides can be tested in routine assays. Applicants also submit that the claims have been amended so that the composition or polypeptide must be capable of binding AGP-3, and that the structural limitations in combination with the limitation regarding the activity of the molecule would not require undue experimentation to practice the invention. Applicants further submit that there is extensive teaching in the specification on how to make polypeptides and muteins that would function as binding partners of AGP-3, that it is well accepted that the binding domain of a TNF receptor like molecule resides in the cysteine rich domain, that the cysteine rich sequences of SEQ ID NOS: 45 and 46 are important for ligand/receptor binding, and that even without working examples, the present invention has satisfied the enablement requirement.

Applicants' arguments have been fully considered but are not deemed persuasive. The basis of the rejection was **not** that it would require undue experimentation to determine what portion of the extracellular domain of AGP-3 receptor would bind AGP-3. The rejection was based on the fact that the claims are limited to protein derivatives that **only** consist of the cysteine rich domains of SEQ ID NOS: 45 and/or 46, and it is not predictable that such small fragments would be able to bind the AGP-3 ligand. The instant application and the prior art have not disclosed the portion(s) of the extracellular domain required for ligand binding, and the cysteine rich domains of SEQ ID NOS: 45 and 46 are likely important in providing the correct three-dimensional spatial orientation of the extracellular domain to allow binding to the ligand, however they may not be directly involved in or sufficient for ligand binding. Applicants assert on page 7 of the amendment that it is well accepted that the binding domain of a TNF receptor

like molecule resides in the cysteine rich domain, however there is no evidence of record that this is the case. Applicants also assert that the specification teaches that the cysteine rich sequences of SEQ ID NOS: 45 and 46 are important for ligand/receptor binding and this is not disputed – they are important. However it is not predictable that they are sufficient for binding.

Applicants further assert that prophetic examples are acceptable, and cite M.P.E.P. 2164.02 and *In re Chilowsky* as support. Applicants' arguments have been considered but are not found persuasive. While it is true that having a working example is not necessarily required to satisfy the enablement requirement in some situations, there are many factors considered when determining if the disclosure satisfies the enablement requirement. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

All the Wands factors are considered and it is the balance of factors that determines whether a disclosure enables the use of the invention. In the previous Office Action, all of these factors were considered.

The MPEP states in section 2164.02:

> ***"Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art."***

In the instant case, there is not enough guidance provided in the specification or the prior art that a cysteine rich domain alone is sufficient for binding a ligand, and therefore the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

7. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

LORRAINE SPECTOR
PRIMARY EXAMINER